DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-898/S-005

Genzyme Corporation
Attention: Naseem Kabir
Manager, Regulatory Affairs
One Kendall Square
Cambridge, MA 02139-7500

26 OCT 2001

Dear Ms. Kabir:

Please refer to your supplemental new drug application dated November 29, 1999, received November 30, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thyrogen (thyrotropin alfa for injection).

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following:

1. Revision to the ADVERSE REACTIONS section of the package insert.
2. Modify the DOSAGE AND ADMINISTRATION and INSTRUCTION FOR USE subsections to clarify that 1.2 mL of WFI should be used for reconstitution. A statement, "Discard the unused portion of the diluent" has also been added.
3. The HOW SUPPLIED section of the package insert and the vial label has been revised to change the NDC number.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted November 29, 1999, immediate container and carton labels submitted November 29, 1999). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research